MEDICAL DEVICE MANUFACTURERS ASSOCIATION

July 30, 2004

Submitted electronically

Ms. Lisa Rovin
Office of the Commissioner (HFP-1)
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Re: Critical Path Initiative [Docket No. 2004-N-0181]

Dear Ms. Rovin:

I appreciate this opportunity to comment on the FDA's Critical Path Initiative, on behalf of the Medical Device Manufacturers Association, a trade association representing the innovative and entrepreneurial sector of the medical device industry. Our members span from startups with products still in development to manufacturers with worldwide distribution. Since the FDA review process plays an integral role in our industry's efforts to bring new and improved products to market, we believe the Critical Path is an important step toward ensuring that patients have quick access to the best and newest safe and effective devices.

The FDA's recent report, "Innovation/Stagnation: Challenge and Opportunity on the Critical Path to New Medical Products," proposes ways to reform and modernize the agency to make the product development process quicker and more predictable. The industry appreciates the FDA's recognition of the challenges along the critical path, including the many hurdles, obstacles, and risks in attempting to bring new and improved devices to market, as well as challenges that remain in the post-market setting.

We remain committed to finding the appropriate balance between ensuring that products are safe and effective, while ensure that the FDA process does not hinder innovation. The myriad pre-market challenges of study design for lab, animal, and human research, represent a daunting process for innovators. To identify bottlenecks and areas of weakness in the critical path, MDMA looks forward to working with the FDA to address these issues.

Specifically, MDMA encourages the FDA to continue and expand the process of reviewing and downclassifying Class II and III products where appropriate, to make better use of the 510(k) process. By easing the FDA's burden for products that require less intensive reviews, the Agency can free up resources to speed up overall review times

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and concentrate on the more complex cases. The industry can be helpful in identifying devices and device categories appropriate for downclassification.

In addition to downclassifications, the FDA should build on improvements mandated by recent device legislation. Improvements should be made in the spirit of the Food and Drug Modernization Act's "least burdensome" requirements, as well as the Medical Device User Fee and Modernization Act's improvements in the area of third-party reviews. In particular, expanding the third-party review program for 510(k) applications with clinical data would free up FDA reviewers' time and add additional streamlining to the review process.

While device makers face a number of challenges in the pre-market setting, barriers also remain in the post-market environment that stifle innovation and limit patient access to the best and latest devices. In fact there are cases where the FDA has cleared or approved an innovative technology, but the manufacturer still has difficulty getting their products to the patients and doctors who need them. This difficulty is a result of certain hospital group purchasing organizations (GPOs) engaging in anticompetitive contracts with a select group of suppliers. These barriers have a direct impact on financial investment in the medical technology segment and while these practices may fall outside the scope of this initiative, they should be dealt with by the Administration. Improving the premarket conditions for medical technology development is only part of the problem. If the goal of the critical path initiative is to improve patient care by streamlining the process to deliver safe and effective medical technologies to the American public, the current GPO system must be reformed by the Administration to promote utilization of innovative products from multiple suppliers, not simply a select few. Otherwise, the incentive to invest in new technologies will lessen innovation will be stifled.

Finally, MDMA would like to again highlight the important differences between devices and the pharmaceutical and biologicals industries. The device innovation and development process includes a different set of hurdles than drugs. Device innovation, for example, tends to be evolutionary rather than revolutionary. As evidenced by the frequency of 510(k) reviews as opposed to PMAs, devices are improved gradually and incrementally. This causes devices to enjoy little or no revenue security in patent protection as new models are constantly being developed. As a result, the average 18-month life cycle ensures that no single device has the same revenue potential of a blockbuster drug. Yet the device development process is just as costly and time-consuming. And small companies are the ones bearing a disproportionate amount of the research and risk of finding novel treatments.

In addition, much of a device's success in early trials depends on practitioner skill. Regardless of the device, the range of abilities of a device's users will result in a less uniform clinical result than, say, prescribing a pill.

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The FDA has taken an important step toward identifying ways in which to help speed access to new medical products. We look forward to working with the FDA to share ideas on how to streamline and improve the review process to insure that patients have access to innovative technologies in a timely fashion.

Sincerely,

Mark Leahey
Executive Director
Medical Device Manufacturers Association

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